REMARKS

Claims 111-170 are pending in the present application. Reconsideration and allowance of the present application in view of the following remarks are respectfully requested.

I. THE CLAIM REJECTIONS UNDER 35 U.S.C. § 103(a) SHOULD BE WITHDRAWN

The pending claims have been rejected under 35 U.S.C. § 103 as allegedly being unpatentable over U.S. Patent No. 5,464,650 to Berg *et al.* (hereinafter "Berg") alone, or Berg in further view of U.S. Patent No. 5,288,711 to Mitchell *et al.* (hereinafter "Mitchell"). For the following reasons, Applicants respectfully disagree.

1. The Legal Standard

A finding of obviousness under 35 U.S.C. § 103 requires a determination of the scope and the content of the prior art, the differences between the invention and the prior art, the level of the ordinary skill in the art, and whether the differences are such that the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. *Graham v. Deere*, 383 U.S. 1 (1966). The relevant inquiry is whether the prior art suggests the invention, and whether one of ordinary skill in the art would have had a reasonable expectation that the claimed invention would be successful. *In re O'Farrell*, 853 F.2d 894, 902-4 (Fed. Cir. 1988); *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Both the suggestion of the claimed invention and the expectation of success must be in the prior art, not in the disclosure of the claimed invention. *In re Dow Chemical Co.*, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988). In determining obviousness, "the inquiry is not whether each element existed in prior art, but whether the prior art made obvious the invention as a whole for which patentability is claimed." *Hartness Int'l Inc. v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 2 U.S.P.Q.2d 1826 (Fed. Cir. 1987). An analysis under 35 U.S.C. § 103(a) "should be made explicit," and "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. __, 2007 WL 1237834, at *14 and *15, respectively (2007).

2. The Claims Are Patentable Over Berg

Claims 111-113, 120-121, 124-125, 129-130, 136-137, 139-143, 150-151, 154-155, 159-160, 166-167, and 169-170 are rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Berg. Specifically, the Examiner first alleges that Berg discloses a wide range of therapeutic substance to polymer ratios (*i.e.*, 10:1 to 1:100) and, thus, suggests a topcoat that is substantially free of an elutable material. (Office Action, p. 4, ¶¶3-4, under "Response to Arguments"). The Examiner then alleges that, since "[t]he present specification discloses criticality in regards to the topcoat ***substantially free*** of an elutable material, and not entirely free of the an elutable material" (Office Action, p.3, ¶3),

> it would be obvious to one of ordinary skill to have the topcoat free of an elutable material because they would expect it to have the same properties as a topcoat substantially free of an elutable material, and it would not require undue experimentation to determine the optimal amount of elutable material within the topcoat.

(Office Action, p. 3, ¶5). For the following reasons, Applicants respectfully disagree.

As discussed below, Applicants respectfully submit that the Examiner has failed to make a *prima facie* case of obviousness against the rejected claims, since Berg fails to teach or suggest each and every element of the rejected claims.

First, Berg does not teach or suggest a topcoat that is substantially free of an elutable material, much less teach or suggest a topcoat that is entirely free of an elutable material. Contrary to the Examiner's allegation, Berg's disclosure of a wide range of therapeutic substance to polymer ratios does not teach or suggest a topcoat that is substantially or entirely free of an elutable material. The Examiner's focus on the lowest endpoint of therapeutic substance to polymer ratio to support the contention that Berg suggests a topcoat being substantially free of an elutable material is improper. The Federal Circuit has counseled against elevating an endpoint of a disclosed range above all other points in a disclosed range. *See Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 1000, 78 U.S.P.Q.2d 1417, (Fed. Cir. 2006) (holding that the disclosure of a range is no more a disclosure of endpoints of a range than it is a disclosure of the intermediate points).

Contrary to the Examiner's allegation, Berg does not teach or suggest a stent having a coating with a topcoat that is free of an elutable material. The disclosure in Berg, as a whole, fails to teach or suggest use of a low ratio of therapeutic substance to polymer, much less teach or suggest use of a ratio well below the lowest ratio disclosed, *i.e.*, no therapeutic substance to polymer. In fact, Berg teaches away from coatings that are free of an elutable

material, since all of Berg's working examples illustrate polymer-containing solutions that result in coating compositions containing a high therapeutic substance to polymer ratio (*i.e.*, 2:1). *See* Berg., col. 6, *l.* 1, to col. 7, *l.* 15. Based on Berg, the skilled artisan would understand that a therapeutic substance *must* be included with a polymer and, thus, would find no suggestion or motivation to exclude a therapeutic substance as suggested by the Examiner. Thus, Berg does not teach or suggest a topcoat that is free of an elutable material.

Moreover, Berg fails to teach or suggest the particular polymer combination used in the undercoat and topcoat of the claimed stents. According to the Manual of Patent Examining Procedure (MPEP) (Eighth Edition, Revision 5, August 2006), in making an obviousness determination, the number of variables which must be selected or modified must be considered, as well as the nature and significance of the differences between the prior art and the claimed invention. See § MPEP 2144.08, subsection II.A.4(c), at page 2100-148; and *see, e.g., In re Jones*, 958 F.2d 347, 350, 21 U.S.P.Q.2d 1941, 1943 (Fed. Cir. 1992).

In particular, Berg fails to teach or suggest selecting a hydrophobic elastomeric material (*e.g.*, ethylene vinyl acetate) to be included in an undercoat of a stent, as recited in the claims. Instead, Berg indiscriminately identifies both hydrophilic (*e.g.*, polyamino acids, fibrin, starch, carboxymethyl cellulose) and hydrophobic (*e.g.*, polyurethanes, silicones) polymers as being suitable for coating a stent. *See* Berg, col. 4, *l.* 35, to col. 5, *l.* 7. Moreover, Berg is silent as to the desirability of having a hydrophobic material in an undercoat of a multilayered stent. Thus, one skilled in the art, in view of Berg, would not find any suggestion or motivation to select a *hydrophobic* elastomeric material to form the undercoat of the claimed stents.

Berg also fails to teach or suggest selecting a *biostable*, non-thrombogenic polymeric material to be included in the topcoat of a stent, as recited in the claims. Berg teaches away from including a biostable polymer in the topcoat. Instead, Berg states that in choosing between a biostable or bioavailable polymer, "a *bioabsorbable* polymer is probably more desirable since, unlike a biostable polymer, it will not be present long after implantation to cause any adverse, chronic local response." *See* Berg, col. 4, *ll.* 39-42 (emphasis added). In fact, all of Berg's working examples illustrate stents formed from a uniform coating composition, comprising bioabsorbable polymers (*e.g.*, polycaprolactone and polylactic acid polymers). *See* Berg, col. 6, *l.* 1, to col. 7, *l.* 15. Thus, one skilled in the art, in view of Berg, would not find any suggestion or motivation to select a *biostable* polymeric material to form

the topcoat of the claimed stents. In addition, Berg never mentions use of a biostable, *non-thrombogenic* polymeric material.

Furthermore, Applicants submit that Berg does not teach or suggest a stent having a coating comprising an undercoat and a topcoat each having a different polymer and different concentration of therapeutic substance wherein the topcoat is free of any therapeutic substance, as recited in the claims. As discussed above, the stents in Berg's working examples were all prepared using a uniform coating composition. None of the stents prepared in Berg's working examples have a plurality of layers having a different polymer and/or a different concentration of therapeutic substance wherein the topcoat is free of any therapeutic substance.

Given the number of variables which must be selected and modified by the skilled artisan, as well as the differences between Berg and the claimed invention, Applicants submit that Berg fails to teach or suggest the claimed stent. For at least the foregoing reasons, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness, and thus, submit that the rejection is in error and should be withdrawn.

3. The Claims Are Patentable Over Berg in Further View of Mitchell

Claims 114-119, 122-123, 126-128, 131-135, 138, 144-149, 152-153, 156-158, 161-165 and 168 are rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Berg in further view of Mitchell. Specifically, the Examiner acknowledges that Berg fails to disclose a coating comprising an antibiotic, but relies on Mitchell for the disclosure of a stent comprising an antibiotic to inhibit proliferation of vascular smooth muscle cells (Office Action, p. 4, ¶1). The Examiner contends that "[i]t would have been obvious to one of ordinary skill in the art to combine the teaching of a stent comprising an antibiotic as taught by Mitchell et al., to a coated vascular stent as per Berg et al." (Office Action, p. 4, *ll.* 4-7). For the following reasons, Applicants respectfully disagree.

As discussed above, Berg fails to teach or suggest a stent having a topcoat that is free of an elutable material. Nor does Berg teach or suggest a stent having the particular polymer combination used in an undercoat and a topcoat, much less teach or suggest a stent having the particular polymer combination and drug concentration in an undercoat and a topcoat. Mitchell fails to remedy these deficiencies. In fact, Mitchell never teaches or suggests a coating being disposed on a stent, much less teach or suggest a stent having more than one coating (*i.e.*, an undercoat and a topcoat) having the particular polymer and drug combination

recited in the claims. Since the combination of Berg and Mitchell fails to teach or suggest each and every element of the claimed stents, Applicants respectfully submit that the claims are patentable over Berg and Mitchell. Thus, the rejection is in error and should be withdrawn.

CONCLUSION

As all rejections are believed to be overcome, all claims are believed to be in condition for allowance. An early notice to that effect would be appreciated. Should the Examiner not agree with Applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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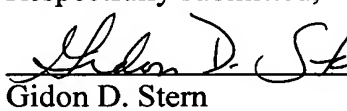

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